REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENT

Claims 1-2, 4-5, 7, and 9-10 were pending in this application when last examined.

Claims 3, 6, and 8 stood cancelled without prejudice or disclaimer thereto.

Claims 1-2, 4-5, 7, and 9-10 were examined on the merits and stand rejected.

Claims 1, 5, 7, and 9-10 are amended herein to clarify the claimed invention. Support for these amendments may be found in the claims as originally filed and, inter alia, in the specification, e.g., paragraph [0004] and Example 3. Claim 1 is amended to incorporate the subject matter of claims 2 and 4, in addition to clarifying that the purity is measured by HPLC and that the CMP-NeuAc-containing solution is a solution is obtained by using CMP-NeuAc synthetase. The remaining amended claims are put into proper dependent form.

Claims 2 and 4 are cancelled herein without prejudice or disclaimer thereto.

No new matter has been added.

II. INDEFINITENESS REJECTION

On pages 2-3 of the Office Action, claims 1-2, 4-5, 7, and 9-10 are rejected under 35 USC 112, second paragraph, as being indefinite.

The Examiner asserts that the precipitated CMP-NeuAc obtained in step (4) of claim 1 is in the form of a salt and thus does not have 95% purity. Applicants respectfully note, however, that the claimed "purity of 95% or more" of CMP-NeuAc is purity measured by HPLC (see, e.g., paragraph [0012] and Example 3). That is, if one completes the claimed process, he/she obtains CMP-NeuAc of high HPLC purity as claimed.

To clarify the above, Applicants have defined "purity" in claim 1 as "purity measured by HPLC". However, please note that the term "purity measured by HPLC" for CMP-NeuAc prepared in the claimed process does not mean the purity after the HPLC *purification* as disclosed in Simon et al. In the claimed process, no HPLC purification is needed to have high purity CMP-NeuAc.

Regarding the dependent claims beginning with "A…", Applicants note that such claims are amended herein to begin "The…".

For the above reasons, Applicants respectfully submit that a skilled artisan can determine the metes and bounds of the claimed invention taking into consideration the teaching of the specification and the knowledge in the art.

Thus, it is respectfully submitted that the rejection is untenable as applied to the amended claims and should be withdrawn.

III. OBVIOUSNESS REJECTION

On pages 3-5 of the Office Action, claims 1-2, 4-5, 7, and 9-10 remain rejected under 35 USC 103(a) as obvious over Simon et al. in view of Warren et al. and Vann et al.

Applicants respectfully traverse this rejection as applied to the amended claims.

The Examiner asserts that the method of Simon et al. does not require the use of chromatography. However, Applicants respectfully note that Simon et al. describes the method including chromatography as "the best way" to remove contaminants such as CTP, PEP, CMP, cytidine, pyruvate, inorganic salts, etc., and to achieve high purity of >95% (page 7161, "Isolation of CMP-NeuAc"). Accordingly, Simon et al. teaches that 95% purity is *only* achieved after purification with HPLC. In other words, the method of Simon et al. *requires* chromatography to achieve high purity.

In contrast, in the claimed process, CMP-NeuAc is purified of contaminants and achieves comparably high purity (≥95%) *without* doing HPLC purification. There is no suggestion in Simon et al. that the claimed process can achieve such high purity without including chromatography, which indicates that the claimed process is unexpectedly advantageous.

To further clarify that the advantageous effect of the claimed process is accomplished in the entire breadth of the claimed invention, Applicants further define the sequence of steps (1) to (4) of claim 1 in accordance with Examples, i.e., by incorporating claims 2 and 4 into claim 1 to define the sequence of steps (1) to (4).

In addition, the difference between the claimed method and Simon's method is further clarified by addition to step (1) of claim 1 the phrase "<u>wherein the CMP-NeuAc-containing</u>

solution is a solution obtained by catalytic reaction of cytidine 5'-triphospate (5'-CTP) and neuraminic acid (NeuAc) by use of CMP-NeuAc synthetase as a catalyst", as supported by paragraph [0004] and Example 3 of the specification.

In Simon et al., CMP-NeuAc was generated with synthetase and the reaction mixture was repeatedly centrifuged and resuspended with NH_4OH, desalted on Biogel P-2, and subjected to ethanol precipitation to collect suspension before the addition of phosphatase and divalent ion (page 7163 of Simon). The purity of CMP-NeuAc prepared in Simon et al is about 90% (page 7163, bottom left column).

Whereas in the claimed method, phosphatase and/or divalent ion is added ***directly*** to a CMP-NeuAc solution obtained from catalytic reaction by synthetase without doing any steps (see, Example 3). The purity of CMP-NeuAc prepared is 95% or higher.

Ergo, according to the claimed invention, higher quality CMP-NeuAc can more easily be prepared compared to Simon et al. Applicants respectfully submit that the above difference and advantageous feature suffice to establish the claimed invention is nonobvious over Simon et al.

For these reasons, Applicants respectfully submit that one of skill in the pertinent art would find no reason in the teachings of the cited references to combine or modify their teachings in order to arrive at the claimed invention, nor would he have any reasonable expectation of success in doing so.

Therefore, the rejection is untenable as applied to the amended claims and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Tomoki HAMAMOTO et al.

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